

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Clinical Laboratory Program
305 South Street, Jamaica Plain, MA 02130
(617) 983-6739 (617) 983-6740 - Fax

BLOOD COLLECTION STATIONS
[PATIENT SERVICE CENTERS]

CHECKLIST

In order to provide assistance to clinical laboratory facilities which desire to open Blood Collection Stations [Patient Service Centers] we have put together a checklist of the most critical areas / responsibilities which we will inspect when we survey the station.

*** * * * * THIS CHECKLIST IS ONLY A GUIDELINE * * * * ***

The clinical laboratory responsible for the Blood Collection Station is responsible for being in compliance with all of the clinical laboratory regulations set forth in 105 CMR 180.000: "Rules and Regulations Relating to the Operation, Approval and Licensing of Clinical Laboratories".

Since the clinical laboratory is responsible for the Blood Collection Station, any deficiencies found during the survey process, will be cited against the clinical laboratory.

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Regulation	Guidelines
I. 180.040 General Requirements	
<p style="text-align: center;">Responsibility of Owners (180.041)</p> <p>The Owner is responsible for the proper maintenance and ethical operation of the collection station and for any violations of these and other regulations.</p>	
<p>Collection Stations (180.042)</p> <p>The collection station is not represented or maintained on behalf of any clinical laboratory unless such laboratory, if in the Commonwealth, is licensed or has been approved as part of a hospital or clinic or unless such laboratory, if not in the Commonwealth, has been accredited or is licensed in accordance with General Law.</p>	
<p>180.042(A)(1)</p> <p>Any permanent area other than the actual facility which is used for the collection of specimens by venipuncture shall be inspected prior to use and a written certificate of approval shall be issued by the department</p>	<p>The laboratory has notified the State Agency prior to opening the collection station? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>(1) An acceptable blood drawing chair or cot, a telephone and adequate hand washing and toilet facilities for employees and patients are available within the station.</p>	<p>Blood drawing chair and/or cot <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Patient bathroom convenient? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Handwashing available <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Telephone? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>(1) A written procedure manual detailing the steps to be followed in the event of an emergency are readily available.</p>	<p>Written protocol available defining the steps to be followed in the event of an emergency? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>(2) Identification signs and advertising is in a manner which does not suggest that the station is a laboratory. Advertising is of an ethical nature and does not contain misleading statements or unsubstantiated claims. Mass advertising is not provided to the general public.</p>	<p>Identification sign? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Sign reads: _____</p>
<p>(2) Laboratory examinations are not performed other than the separation of plasma and serum and other such approved preparative procedures.</p>	
<p>(3) The director or his designee is responsible for all aspects of the station and is available during all hours of operation and makes periodic personal inspections of the station to insure suitable handling of patients and specimens and instructs employees in such matters and in the most recent improvements in technique.</p>	<p>Documentation of supervisor/site manager visits? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>(3) Technical employees are proficient in venipuncture, specimen processing, and emergency procedures as required.</p>	

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II. 180.250 Management	
Procedure Manual (180.255) Adequate procedures governing collection, preservation, and transportation of specimens to assure stability are readily available and provided to patients when necessary.	
(1) Manuals are reviewed and dated at least annually and written approval of all changes is given by the director	Specimen requirements manual? <input type="checkbox"/> Yes <input type="checkbox"/> No Date of last review: ____/____/____
Facility Management (180.260) Space and facilities are adequate to properly perform the services offered.	
(1) Workbench space is ample, well lighted and convenient to sink, water, gas, suction and electrical outlets as necessary.	
(2) Work areas are arranged to minimize problems in transportation and communication. Ventilation is adequate.	
(3) Volatile chemicals and inflammable solvents are properly stored in areas unlikely to ignite same or restricted from open flame or heat	
(4) Appropriate enclosures are utilized when handling hazardous materials.	
(5) Adequate fire prevention and occupational safety and health laws are known, posted and observed insuring that there is freedom from unnecessary physical, chemical, and biological hazards.	Fire extinguisher? <input type="checkbox"/> Yes <input type="checkbox"/> No Sprinkler system? <input type="checkbox"/> Yes <input type="checkbox"/> No Food (glucola) stored in specimen refrigerator? <input type="checkbox"/> Yes <input type="checkbox"/> No Fire and safety policies and procedures? <input type="checkbox"/> Yes <input type="checkbox"/> No Exit sign posted? <input type="checkbox"/> Yes <input type="checkbox"/> No
There is documentation of preventative maintenance, periodic inspection and testing for proper operation of equipment.	Date of last speed check for centrifuge ____/____/____ Speed ____
Temperature controlled spaces and equipment are monitored with respect to all critical operating characteristics and appropriate records are maintained.	<input type="checkbox"/> Refrigerator <input type="checkbox"/> Freezer <input type="checkbox"/> Incubator Thermometer available? <input type="checkbox"/> Yes <input type="checkbox"/> No Temperature records maintained? <input type="checkbox"/> Yes <input type="checkbox"/> No
All reagents and solutions are labeled to indicate identity and when significant titer, strength or concentration, recommended storage requirements, preparation and expiration date and other pertinent information. Materials of substandard reactivity are not used.	
Collection of Specimens 180.265 No person other than a licensed MD or an individual authorized by a qualified lab director or individual authorized by law may collect blood or other specimens.	

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<p style="text-align: center;">Sterilization 180.270</p> <p>(B) Disposable syringes, needles, pipettes, petri dishes, and other disposable items are appropriately discarded immediately after use.</p>	
<p style="text-align: center;">Disposal of Infectious Materials (180.275)</p> <p>Disposal of all materials of a potentially infectious nature is carried out in accordance with waste disposal regulations specified in 105 CMR 480.000.</p>	<p>Infectious waste vendor: _____</p> <p>Manifests available and maintained appropriately? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p style="text-align: center;">Examination and reports (180.280)</p> <p>Specimens are obtained and received only at the written request of a licensed physician or other person so authorized.</p>	
<p>(A) If a patient is sent to the laboratory, a written request for the desired laboratory procedures shall be obtained by the laboratory from a person authorized by law to use findings of laboratory examinations.</p>	
<p>(B) A specimen delivered to a laboratory shall be accompanied by a written request.</p>	
<p style="text-align: center;">Specimen Records (180.285)</p> <p>Records are maintained which indicate the daily accession of specimens, each of whom is numbered or otherwise appropriately identified.</p>	<p>Accession log maintained? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Manual log <input type="checkbox"/> Entered via computer</p>
<p>(a-f) Records include laboratory number or other identification of the specimen, identification of the patient and the person or laboratory who submitted the specimen, dates of collection and reception and the condition of unsatisfactory specimens.</p>	<p>Stat test protocol: <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Time of collection is recorded where appropriate. (recommendation)</p>	
<p style="text-align: center;">Personnel Policies (180.295)</p> <p>Written personnel policies, practices and procedures that support sound laboratory practice are available. Employee work assignments are consistent with qualifications.</p>	<p>Personnel policies? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Written job description for phlebotomist? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>